AMENDMENT TO THE CLAIMS

1. (Currently Amended) A computer-implemented system that integrates data from a plurality of biomedical development phases, comprising:

a database that stores data collected from the biomedical development phases,

said database further including a first metadata data structure that describes the data collected during a first biomedical development phase;

a plurality of graphical user interfaces for collecting data relating to the biomedical development phases, wherein the plurality of graphical user interfaces are specific to different ones of the biomedical development phases;

the plurality of graphical user interfaces including at least one first graphical user interface connected to the database that collects data during the first biomedical development phase, wherein structure of the first graphical user interface is defined based at least in part upon the first metadata data structure so that the first graphical user interface collects data points as well as first metadata that is to be stored within the first metadata data structure, said first metadata describing the collected data points,

wherein at least a portion of the first metadata data structure is configured to provide information for a subsequent biomedical development phase,

wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent biomedical development phase so that an audit trail may be generated, the links including at least one of patient identification metadata and study identification metadata ~~metadata that indicates how the collected data interrelates with the subsequent biomedical development phase.~~;

wherein the plurality of graphical user interfaces are configured to collect at least one of the patient identification metadata and the study identification metadata for each of the biodevelopment phases such that the patient identification metadata or the study identification metadata may be used as linking data to indicate how the collected data interrelates with other data collected during the subsequent biomedical development phase.

2. (Original) The system of claim 1 wherein the biomedical development phases include phases selected from the group consisting of discovery phase, clinical studies phase, Food and Drug Administration (FDA) approval phase, product release phase, and combinations thereof.

3. (Cancelled)

4. (Original) The system of claim 2 wherein the first biomedical development phase is a discovery phase, wherein the first metadata data structure includes data for specifying how often during the first biomedical development phase test measurements were obtained and units associated with the test measurements.

5. (Original) The system of claim 4 wherein the first metadata data structure includes data for specifying data manipulations performed upon data collected during the first biomedical development phase.

6. (Original) The system of claim 5 wherein the specified data manipulations include data unit conversion operations.

7. (Original) The system of claim 4 wherein the first metadata data structure contains data that specifies interrelationships between tests conducted during the first biomedical phase.

8. (Cancelled)

9. (Original) The system of claim 4 further comprising:

a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase.

10. (Previously Amended) The system of claim 9 further comprising:

at least one second graphical user interface connected to the database that collects data during the second biomedical development phase, wherein structure of the second graphical user interface is defined based at least in part upon the second metadata data structure so that the second graphical user interface collects data points as well as second metadata that is to be stored within the second metadata data structure, said second metadata describing the collected data points,

wherein at least a portion of the second metadata is configured to provide information for a biomedical development phase that occurs approximately subsequently to the second biomedical phase.

11. (Original) The system of claim 10 wherein the second biomedical development phase is a clinical studies phase, wherein the second metadata data structure includes data that specifies interrelationships between tests conducted during the second biomedical development phase.

12. (Original) The system of claim 11 wherein data links exist between the first metadata stored in the first metadata data structure and the second metadata stored in the second metadata data structure in order to form an audit trail.

13. (Original) The system of claim 12 wherein the audit trail is used during an FDA approval phase to determine a biomedical product development audit trail associated with the first and second biomedical development phases.

14. (Original) The system of claim 13 wherein the first metadata is used during an FDA approval phase to determine how tests were conducted during the first biomedical development phase, wherein the second metadata is used during the FDA approval phase to determine how tests were conducted during the second biomedical development phase.

15. (Original) The system of claim 12 wherein the first metadata is used during an FDA approval phase to determine how tests were conducted during the first biomedical development phase, wherein the second metadata is used during an FDA approval phase to determine how tests were conducted during the second biomedical development phase.

16. (Previously Amended) The system of claim 12 wherein the first biomedical development phase is the discovery phase, wherein at least a portion of the first metadata data structure is configured to provide information for the FDA approval phase.

17. (Previously Amended) The system of claim 16 wherein the information provided for the FDA approval process that defines at least a portion of the first metadata data structure relates to an FDA requirement that patients be tested who are taking a predetermined medication.

18. (Previously Amended) The system of claim 12 wherein the second biomedical development phase is the clinical studies phase, wherein at least a portion of the second metadata data structure is configured to provide information for a third party evaluating the biomedical product associated with the second biomedical development phase.

19. (Original) The system of claim 18 wherein the third party is a party selected from the group consisting of another company division, a different company, the FDA, and combinations thereof.

20. (Original) The system of claim 1 wherein the first metadata data structure includes links between unstructured biomedical data and structured biomedical data.

21. (Original) The system of claim 20 wherein the unstructured biomedical data includes data contained in word processing documents and handwritten notes.

22. (Original) The system of claim 1 further comprising:

a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase;

a third metadata data structure contained within the database that describes the data collected during a third biomedical development phase, said third biomedical development phase occurring approximately after the second biomedical development phase; and

a fourth metadata data structure contained within the database that describes the data collected during a fourth biomedical development phase, said fourth biomedical development phase occurring approximately after the third biomedical development phase.

23. (Cancelled)

24. (Cancelled)

25. (Original) The system of claim 22 wherein the first and second metadata data structures include data structures that specify what data manipulations were performed upon data collected during their associated biomedical development phases.

26. (Original) The system of claim 22 wherein the first and second metadata data structures include data structures that specify interrelationships between tests conducted within their associated biomedical development phases.

27. (Original) The system of claim 1 further comprising:

a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase;

a third metadata data structure contained within the database that describes the data collected during a third biomedical development phase, said third biomedical development phase occurring approximately after the second biomedical development phase;

a fourth metadata data structure contained within the database that describes the data collected during a fourth biomedical development phase, said fourth biomedical development phase occurring approximately after the third biomedical development phase; and

a web portal entry point to the database, wherein users access data contained within the first, second, third and fourth metadata data structures through the web portal entry point.

28. (Original) The system of claim 27 wherein the database includes a plurality of biomedical projects, wherein the biomedical projects have their respective first and second metadata stored in the database, wherein a data warehouse contains the database.

29. (Original) The system of claim 28 wherein a first company has rights to a first biomedical project, said system further comprising:

an identifier that identifies data and metadata as associated with the first biomedical project and owned by the first company.

30. (Original) The system of claim 27 wherein the identifier is a uniform resource locator (URL) that identifies data and metadata as associated with the first biomedical project and owned by the first company.

31. (Original) The system of claim 30 wherein a second company has rights to the first biomedical project by accessing the URL associated with the first biomedical project.

32. (Original) The system of claim 31 wherein a security mechanism is associated with the URL such that the first company is precluded from access to the data and metadata of the first biomedical project after the project's ownership is transferred from the first company to the second company.

33. (Original) The system of claim 32 wherein the security mechanism includes a user name and password mechanism.

34. (Original) The system of claim 1 further comprising:

a biomedical data warehouse that contains the database;

a genomic data warehouse that stores genomic data; and

data links between data in the biomedical data warehouse and data in the genomic data warehouse,

wherein genomic data is used to analyze data stored in the biomedical data warehouse via the data links.

35. (Cancelled)

36. (Cancelled)

37. (New) The computer-implemented system of claim 1, further comprising:

a genomic data warehouse that stores genomic information relating to a plurality of patients, the genomic data warehouse including a genomic metadata data structure that describes the genomic information and that includes patient identification metadata;

wherein the patient identification metadata in the genomic metadata structure is used to link genomic information in the genomic data warehouse with data collected during the plurality of biomedical development phases.

38. (New) The computer-implemented system of claim 37, further comprising:

an adverse reaction analysis module that relates the genomic information from the genomic data warehouse with the data collected during the plurality of biomedical development phases to analyze adverse reactions to a product resulting from the biomedical development phases.